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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,488	12/21/2000	Steven M. Bowman	22956-67	8271

21125 7590 03/12/2003
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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/12/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,488

Applicant(s)

BOWMAN ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt of Applicant's amendment and information disclosure statement, filed on January 14, 2003, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title; if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (U.S. Patent 6,179,872).

Bell et al. discloses biopolymer matt compositions comprising various layers of biopolymer foams for use as prostheses, implants or scaffolds (See col. 1, lines 24-55). Bell et al. teaches that the porosity of matt can be manipulated by various physical or chemical methods (See col. 2, lines 27-31). Bell et al. teaches that the foam layer has low density and high porosity and the matt composition can incorporate fiber structures to achieve general reinforcement (See col. 3, lines 10-56), and, specifically, biopolymers can be used to create matts, which can be supported by polymer mesh (See col. 5, lines 56-64). Bell et al. teaches that macromolecules can be added to the biopolymer to promote cell ingrowth and tissue development, and includes growth factors, proteins, glycosaminoglycans, polysaccharides and living cells among the molecules used in the invention (See col. 6, line 12 to col. 7, line 25). Bell et al. explains that the biopolymer foams can be single density or double density foams, which have a higher biopolymer density per unit

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volume than the single density foams, can be bonded to a polymer mesh and serve as substrate for cell attachment and growth (See col. 7, line 65 to col. 9, line 6). Bell et al. teaches that the use of alginic acid results in a porous material having a network of interconnecting pores in a sponge-like structure, and the strength of the matt can be increased by laying reinforcing material into the fibrils, including biopolymer fabrics of a selected size and density (See col. 11, lines 36-62).

Thus, Bell et al. provides an implant comprising a foam component, a reinforcing component and a biological component and contemplates varying the porosity the composition. Bell et al. does not specifically disclose the mesh density of the composition, however, it teaches that the strength of the matt can be increased by laying reinforcing material into the fibrils, including biopolymer fabrics of a selected size and density. Thus, one of ordinary skill in the art would have been able to determine the optimal mesh density by routine experimentation. Bell et al. does not specifically mention that the concentration of the biological component can be different in the various layers of the composition, however, it contemplates including the active agent in a coating solution applied at the surface of the matt composition (See col. 15, lines 3-30). One of ordinary skill in the art would have been able to determine the optimal concentration of the active agent in the different layers by routine experimentation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Bell et al. to device an implant comprising foam, reinforcing component and active agent to promote regeneration of damaged tissue. The expected result would have been a successful implant. Because of the teachings of Bell et al.,

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that biological scaffolds comprising foam layers, reinforcing structure and active agent can be used for tissue repair, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

3. Applicant's arguments, filed on January 14, 2003, have been fully considered, but found only partially persuasive.

4. Applicant argues that Bell et al. fails to teach that the pores of the foam penetrate and interlock with the mesh of the reinforcing component, and the reference does not teach or suggest a reinforcing component having a 12-80% mesh density. In response to said arguments, it is noted that Bell et al. provides the general teachings that the matt composition can incorporate fiber structures to achieve general reinforcement (See col. 3, lines 10-56), and, specifically, biopolymers can be used to create matts, which can be supported by polymer mesh (See col. 5, lines 56-64). Bell et al. teaches that the biopolymer foams can be bonded to a polymer mesh (See col. 8, lines 60-64) and the strength of the matt can be increased by laying reinforcing material into the fibrils, including biopolymer fabrics of a selected size and density (See col. 11, lines 36-62). Thus Bell et al. teaches that the reinforcing material can penetrate into the fibrils and the mesh density can be selected to be in the desired range.

5. Applicant's arguments with respect to the teachings of Arnold have been fully considered and found persuasive, since the reference does not teach or suggest the mesh density.

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Accordingly, the 35 U.S.C. 103(a) rejection of claims 1-17 over Arnold of the previous Office action has been withdrawn.

Conclusion

6. Claims 1-17 stand rejected.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the


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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LSH

February 27, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER-1600